K032981

Premarket Notification [510(k)] Summary
as required by 21 CFR 807.92

Date summary was prepared:

March 27, 2003

Submitter's Name:

Varian Medical Systems
3100 Hansen Way
Palo Alto, CA 94304

Contact Person:

Vy Tran
Manager, Regulatory Affairs
Phone   (650) 424-5731
FAX   (650) 842-5040
E-mail vy.tran@varian.com

Device Name:

Eclipse

Classification Name:

System, Planning, Radiation Therapy Treatment

Predicate Device:

Eclipse 6.5, K010975

Product Description:

The Varian Eclipse is a computer-based device used for calculating and displaying prospective or verification treatment plans for particular patient undergoing a course of radiation therapy. The system consists of a computer with graphics display, plotter output, film scanner and backlit digitizer input.

Eclipse provides the capabilities diagnostic image analysis, contouring and segmentation and dosimetric plan review. In addition Eclipse provides tools for photon and electron dose calculation and photon dose compensation. Dose distribution from external beam, intracavitary and interstitial plans (created in BrachyVision [K992762], which can be sold as an option with Eclipse) can be combined together.

Eclipse integrates treatment planning with Varian Vision applications.

Intended Use:

The Varian Eclipse device is a treatment planning system used for diagnostic image analysis, contouring & segmentation, geometrical planning, photon and electron dose calculation and plan review.

Technological Characteristics:

Specification Comparison Chart

Predicate Device	New Device
Varian Eclipse 6.5 (build 7.0) K010975	Varian Eclipse
The Varian Eclipse device is a treatment planning system used for diagnostic image analysis, contouring & segmentation, geometrical planning, photon and electron dose calculation and plan review.	The Varian Eclipse device is a treatment planning system used for diagnostic image analysis, contouring & segmentation, geometrical planning, photon and electron dose calculation and plan review.
1. General Software	1. General Software
Coplanar and Non-coplanar Photon Beams	Coplanar and Non-coplanar Photon Beams
Coplanar and Non-coplanar Electron Beams	Coplanar and Non-coplanar Electron Beams
Isocentric, fixed SSD and Arc fields	Isocentric, fixed SSD and Arc fields
Asymmetric collimators	Asymmetric collimators
Multileaf Collimators	Multileaf Collimators
Cerrobend blocks	Cerrobend blocks
Hard Wedges, Dynamic Wedge and Enhanced Dynamic Wedge	Hard Wedges, Dynamic Wedge and Enhanced Dynamic Wedge
Oblique Planar Reconstruction	Oblique Planar Reconstruction
Dose Volume Histograms	Dose Volume Histograms
3D Graphics Visualization	3D Graphics Visualization

Configurable Treatment Unit Scales	Configurable Treatment Unit Scales
Digitally Reconstructed Radiographs	Digitally Reconstructed Radiographs
Fully Integrated to the Varis Vision database	Fully Integrated to the Varis Vision database
VariSource afterloader plan summation	VariSource afterloader plan summation
Physical Compensators	Physical Compensators
Plan library to store and retrieve common plans	Plan library to store and retrieve common plans
2. Contouring Tools	**2. Contouring Tools**
Freehand	Freehand
Rubberband	Rubberband
Pre-defined geometrical shapes	Pre-defined geometrical shapes
Eraser	Eraser
Cut and Paste	Cut and Paste
Rotate	Rotate
Scale	Scale
Mirror	Mirror
Automatic Contour	Automatic Contour
3D Automargin	3D Automargin
3. Display	**3. Display**
Graphical User Interface	Graphical User Interface
Property Sheets for easy screen navigation	Property Sheets for easy screen navigation
Toolbars for frequently used operations	Toolbars for frequently used operations
Layer window to show and select fields/accessories	Layer window to show and select fields/accessories
Open GL Graphics support	Open GL Graphics support
4. Geometric Planning	**4. Geometric Planning**
CT Simulation functionality	CT Simulation functionality
Isocenter Placement	Isocenter Placement
▪ Automatic via target geometry	▪ Automatic via target geometry
Block Fitting	Block Fitting
MLC Fitting	MLC Fitting
"Pick & Grab" Interactive Field Placement	"Pick & Grab" Interactive Field Placement
Field Parameters Spreadsheet	Field Parameters Spreadsheet
5. Visualization	**5. Visualization**
Image Planes:	Image Planes:
▪ Axial	▪ Axial
▪ Coronal	▪ Coronal
▪ Sagittal	▪ Sagittal
▪ Oblique	▪ Oblique
CT/MRI Image Registration	CT/MRI Image Registration
Beam Overlays	Beam Overlays
MLC Overlays	MLC Overlays

Cerrobend Block Overlays	Cerrobend Block Overlays
3D View:	3D View:
MLC	MLC
Blocks	Blocks
Beams	Beams
Wedges	Wedges
Anatomical Structures	Anatomical Structures
Beam's Eye View (BEV):	Beam's Eye View (BEV):
Field Geometry	Field Geometry
Anatomical Structures	Anatomical Structures
Wedge Orientation	Wedge Orientation
MLC Leaves	MLC Leaves
Digitally Reconstructed Radiograph (DRR)	Digitally Reconstructed Radiograph (DRR)
Anatomical Structure Visualization:	Anatomical Structure Visualization:
Wire Frame	Wire Frame
Translucent	Translucent
Solid	Solid
User Definable Color	User Definable Color
Machine Orientation Icon	Machine Orientation Icon
Patient Orientation Icon	Patient Orientation Icon
Measurement Tools:	Measurement Tools:
CT/Pixel Values	CT/Pixel Values
Distances	Distances
Angles	Angles
Areas	Areas
Volumes	Volumes
Point dose	Point dose
Line dose	Line dose
6. Calculation Algorithms	**6. Calculation Algorithms**
Photons:	Photons:
Energy range: 1MV – 50MV	Energy range: 1MV – 50MV
Single Pencil Beam Convolution Model	Single Pencil Beam Convolution Model
MU Calculations	MU Calculations
Heterogeneity Corrections:	Heterogeneity Corrections:
Batho Power Law	Batho Power Law
Equivalent TAR	Equivalent TAR
Electrons:	Electrons:
Energy range: 1MeV – 50MeV	Energy range: 1MeV – 50MeV
Generalized Gaussian Pencil Beam Model	Generalized Gaussian Pencil Beam Model
	Electron Monte Carlo dose calculation model (based on Macro Monte Carlo algorithm)
Non-CT based Irregular field planning support	Non-CT based Irregular field planning support

Protons: None	Protons: None
7. Import/Export Features	**7. Import/Export Features**
Image & Contour Data import Interfaces:	Image & Contour Data import Interfaces:
• DICOM including RT objects (Ethernet Local Area Network)	• DICOM including RT objects (Ethernet Local Area Network)
• CART format	• CART format
• TIFF format	• TIFF format
• BMP Format	• BMP Format
• Configurable pure pixel data	• Configurable pure pixel data
• PortalVision Mark 1&2 (not used with Protons)	• PortalVision Mark 1&2 (not used with Protons)
• Varian CT Option	• Varian CT Option
• Electromagnetic Digitizer	• Electromagnetic Digitizer
• Film Scanner	• Film Scanner
Export Interfaces:	Export Interfaces:
• DICOM including RT objects	• DICOM including RT objects
• MLC Shaper files	• MLC Shaper files
• Blocks and Compensator data to Par Scientific	• Blocks and Compensator data to Par Scientific
• Plan and dose data to Picker AcQSim	• Plan and dose data to Picker AcQSim
• Integrated with Varis verification system	• Integrated with Varis verification system
• ASCII File to Laser System	• ASCII File to Laser System
• Varian CadPlan Plus 6.0	• Varian CadPlan Plus 6.0
8. Plan Review	**8. Plan Review**
2D Plan Display:	2D Plan Display:
• Isodose Lines	• Isodose Lines
• Color Wash	• Color Wash
3D Plan Display:	3D Plan Display:
• Isodose Surfaces (Wire Cage, Translucent, Solid)	• Isodose Surfaces (Wire Cage, Translucent, Solid)
• Dose Color Wash	• Dose Color Wash
• Organ Surface Dose	• Organ Surface Dose
Dose Volume Histograms:	Dose Volume Histograms:
• Cumulative	• Cumulative
• Differential	• Differential
Plan Comparison:	Plan Comparison:
• DVH	• DVH
• Visual side by side	• Visual side by side
• Dose difference	• Dose difference
Plan Summing	Plan Summing
• External plans	• External plans
• Brachytherapy plans	• Brachytherapy plans

9. Plan Output – Hardcopy	9. Plan Output – Hardcopy
Graphics window screen dump	Graphics window screen dump
Treatment plan output includes:	Treatment plan output includes:
• Patient administration data	• Patient administration data
• Time stamp	• Time stamp
• Field parameters	• Field parameters
• Dose parameters	• Dose parameters
• Patient orientation	• Patient orientation
• Plot scale	• Plot scale
• Treatment protocol list	• Treatment protocol list
User Configurable hardcopy layouts	User Configurable hardcopy layouts
Configurable Treatment Unit Scales	Configurable Treatment Unit Scales
Letter, tabloid, A4 and A3 paper sizes	Letter, tabloid, A4 and A3 paper sizes
Plotting of BEV image at user defined MAG factor	Plotting of BEV image at user defined MAG factor

JUL 2 4 2003

Ms. Vy Tran
Regulatory Affairs Manager
VARIAN Medical Systems, Inc.
3100 Hansen Way
PALO ALTO CA 94304-1038

Re: K030981
    Trade/Device Name: Eclipse
    Regulation Number: 21 CFR 892.5050
    Regulation Name: Medical charge-particle radiation therapy system
    Regulatory Class: II
    Product Code: 90 MUJ
    Dated: March 27, 2003
    Received: March 28, 2003

Dear Ms. Tran:

This letter corrects our substantially equivalent letter of June 24, 2003 regarding the incorrect product code. In the original letter the product code was stated as LNH and MUJ, it should have been just MUJ. This error has been corrected in our files.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent for the indications for use stated in the enclosure to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4654. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon
Director, Division of Reproductive,
  Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): _K∅ 3∅9 8/_

Device Name: Eclipse

Indications For Use:

The Varian Eclipse device is used to plan photon and electron radiation therapy treatments employing linear accelerators and other similar radiotherapy devices with x-ray energies from 1 – 50MV, as well as Cobalt-60 and electron energies from 1 – 50MeV. Eclipse will plan the 3D radiotherapy treatment approaches to combined modality plans, coplanar and non-coplanar fields, static and ARC fields, beam modifiers and beam intensity modulators.

Eclipse includes also tools for treatment preparation (diagnostic image analysis, contouring and segmentation) and plan review.

As part of the VARiS Vision System, Eclipse integrates the treatment planning in overall therapy process, while taking advantage of the Varian Vision database.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

Prescription Use ✓

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number _____ K∅3C98 |